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April 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99D-0557

Gentlemen:

I recently read the FDA's published "Guidance for Industry" in the Federal Register for "Public Health Issues Posed by the Use of Human Primate Xenographs in Humans" wherein the FDA again acknowledged the dangers of using non-human primates as donors in xenotransplants and suggested that clinical protocols proposing the use of nonhuman primate xenographs should not be submitted to the FDA until sufficient scientific information exists addressing the risks posed by nonhuman primate xenotransplants.

I am writing to urge you to take a similar position on other species, particularly pigs, and in support of that request would point out the following:

- The threat of inter-species virus transmission is present in all species not just nonhuman primates. There is no evidence that pigs are any safer than nonhuman primates. In fact, there is plenty of evidence that pig viruses would be just as dangerous as nonhuman primate viruses (i.e., influenza, PERVs, paramyxovirus and, more recently, the Nipah [Hendra-like virus] in Malaysia that has resulted in hundreds of human infections and deaths).
- In January of this year, the Council of Europe, representing 40 European countries, recommended a world-wide ban on all xenotransplants.

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- There are safer and more humane alternatives to xenotransplantation which are yet to be explored by regulatory authorities including the aggressive promotion of preventive medicine and increasing human organ donation rates through various legislative schemes. The GAO recently reported the untapped donor pool in the U.S. to be around 150,000.

In closing, I ask that the FDA ban all xenotransplants.

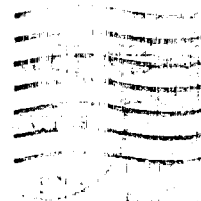
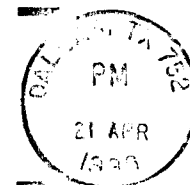
Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert L. Trimble", written in a cursive style.

Robert L. Trimble

/jc(lh)

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